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Filed : February 27, 2004

REMARKS

Interview Summary

Applicant thanks the Examiner for the courteous interview conducted on January 9, 2006, and the helpful comments provided therein. In the Interview, the Examiner agreed that an amendment to Claim 1 to recite that the claimed transdermal delivery system is formulated in the absence of alcohol would be allowable. The Examiner also agreed to permit Applicant to submit additional claims directed to the delivered agent has a molecular weight of 1000 daltons or more. Applicant agreed to remove the term "delivery agent" from the claims and the specification, and to substitute it therewith the term "delivered agent." Applicant also agreed to cancel claims directed to treatment of Alzheimer's disease and cancer. Applicant also agreed to file a Terminal Disclaimer in this case to address the obviousness-type double patenting rejections.

Amendments

The specification has been replaced with the substitute specification. The changes to the specification are indicated. Specifically, the references to "delivery agent(s)" have been replaced by "delivered agent(s)" in accordance to the Examiner's request. Accordingly, no new matter has been introduced.

Claims 3, 17, 22, 23 and 26 are canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicant maintains that the cancellation of a claim makes no admission as to its patentability and reserves the right to pursue the subject matter of the cancelled claim in this or any other patent application.

Claims 1, 4, 5, 6, 8, 9, 10, 18, 19, 27, 28, 29, 30 and 31 are amended. Claims 1, 6, 8, 9, 10, 29, 30 and 31 are amended to replace the term "delivery agent" with the term "delivered agent." Support for this amendment is found throughout the specification and the claims as originally filed. Claim 1 also is amended to indicate that the claimed transdermal delivery system is formulated in the absence of alcohol. Support for this amendment is found in the specification, for example, at page 6, lines 10-11; page 19, line 29 through page 20, line 17; page 21, lines 4-8; and Table 3 at page 33. Claim 9 also is amended to indicate that the delivered agent can be collagen or a fragment thereof. Support for this amendment is found in the specification, for example, at page 16, lines 10-19. Claims 4, 5, 18, 19, 27 and 28 have been

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amended to more clearly indicate that the recited oils are ethoxylated. Support for this amendment is found in the specification, for example, on page 20, lines 2-3. The amendments to the claims do not add new matter.

New Claims 36-67 are added. New Claims 36-42 recite particular molecular weight ranges of the delivered agent. Support for new Claims 36 and 43 is found in the specification, for example, at page 9, lines 9-21; page 16, lines 17-19; and page 35, lines 15-17. Support for new Claims 37 and 50 is found in the specification and in the claims as originally filed, for example, original Claim 11. Support for new Claims 38 and 51 is found in the specification, for example, at page 35, lines 17-21. Support for new Claims 39 and 52 is found in the specification, for example, at page 15, lines 1-4. Support for new Claims 40 and 53 is found in the specification, for example, at page 4, lines 23-24. Support for new Claims 41 and 54 is found in the specification, for example, at page 5, lines 26-29. Support for new Claims 42 and 55 is found in the specification, for example, at page 2, lines 22-25. Support for new Claims 44-49 is found in the specification and the claims as originally filed, for example, Claims 2-9. Support for new Claims 56-67 is found in the specification, for example at page 9, lines 9-21. The new claims do not add new matter.

Upon entry of the amendment, Claims 1, 2, 4-16, 18-21, 24, 25 and 27-67 are pending.

Rejection under 35 U.S.C. §112, First Paragraph - Enablement

Claims 22 and 23 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the claimed methods of treating or preventing cancer or Alzheimer's disease are not enabled by the specification because there is no disclosure that shows treatment of the recited conditions.

Applicant has canceled Claims 22 and 23 herein. Applicant maintains that the cancellation of a claim makes no admission as to its patentability and reserves the right to pursue the subject matter of the cancelled claim in this or any other patent application. In view of the cancellation of these claims, this ground for rejection of the claims is now moot.

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Rejection under 35 U.S.C. §112, First Paragraph – Written Description

Claims 1-35 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action has objected to use of the term “delivery agent.”

In conformance with the Examiner’s suggestion, Applicant has removed the phrase “delivery agent” and substituted therewith the phrase “delivered agent” throughout the claims. Similar substitutions have been made throughout the specification.

In view of the amendments to the claims and the specification, Applicant respectfully submits that this ground for rejection of the claims is now moot.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 4, 5, 18, 19, 27 and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office Action indicates that recitation of “ethoxylated oil comprises an oil selected from the group consisting of castor oil, jojoba oil, corn oil, and emu oil” is vague and indefinite.

In conformance with the Examiner’s suggestion, Applicant has amended Claims 5, 19 and 28 to insert the descriptor “ethoxylated” in front of castor, jojoba, corn, and emu oil. A similar amendment has been made to Claims 4, 18 and 27 to insert the descriptor “ethoxylated” in front of animal and vegetable. Applicant submits that this amendment to the claims is for purposes of clarification only and does not change the scope of the claims in any way.

In view of the amendment to the claims, Applicant respectfully submits that this ground for rejection of the claims is now moot.

Rejection under Obviousness-Type Double Patenting

Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2, 6, 7, 18, 24-32, 49, 55, 56, 65-68 and 70-72 of copending Application Serial No. 10/856,567. The Office Action indicates that the rejected claims of the instant application are not patentably distinct from the cited claims of this copending patent application.

Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 4-14, 17-22 and 25-

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31 of U.S. Patent No. 6,759,056. The Office Action indicates that the rejected claims of the instant application are not patentably distinct from the cited claims of this patent.

Claims 1-4, 6, 7-15, 18, 20-24 and 31-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 9 and 17-23 of U.S. Patent No. 6,946,144. The Office Action indicates that the rejected claims of the instant application are not patentably distinct from the cited claims of this patent.

Applicant submits herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321(c), disclaiming any term beyond the expiration date of the full statutory term of Application Serial No. 10/856,567 or U.S. Patent Nos. 6,759,056 or 6,946,144, and agreeing that any patent so granted on the above-captioned application shall be enforceable only for and during such period that the owner of the legal title to said patent shall be the same as that of the legal title to Application Serial No. 10/856,567 or U.S. Patent Nos. 6,759,056 or 6,946,144. In view of submission of this Terminal Disclaimer, Applicant respectfully requests removal of this rejection.

Rejection under 35 U.S.C. §102(b)

Claims 1-7 and 15-21 are rejected under 35 U.S.C. §102(b), as being anticipated by Toppo, U.S. Patent No. 5,318,960. The Office Action indicates that Toppo discloses all elements of these claims.

Claim 1, as amended, is directed to a transdermal delivery system comprising an ethoxylated oil and a delivered agent formulated in the absence of alcohol. Applicant submits that Claim 1 is novel over Toppo. Toppo does not disclose a transdermal delivery system that is formulated in the absence of alcohol. In fact, Toppo discloses the opposite, teaching that “[e]ach of the materials, the oil-surfactant, co-solubilizer alcohol and water is important in all of the above formulations.” Toppo at column 3, lines 23-25 (emphasis added). Thus, Toppo does not disclose all elements of the transdermal delivery system of Claim 1. Accordingly, Toppo cannot anticipate Claim 1.

Claims 2-7 depend from Claim 1. Claim 15 is directed to a method of reducing pain or inflammation by identifying a subject in need of a reduction in pain or inflammation, and providing to the subject a transdermal delivery system according to Claim 1. Claims 16-21 depend from Claim 15. Accordingly, Claims 2-7 and 15-21 include the transdermal delivery system that is formulated in the absence of alcohol. As discussed above, Toppo cannot anticipate

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Claim 1. Because Claims 2-7 and 15-21 include the transdermal delivery system as recited in Claim 1, Toppo also cannot anticipate these claims.

Applicants respectfully submit that new Claims 36-42 and 56-67 are also not described or suggested by Toppo because they include the limitations of Claim 1. Furthermore, Applicant respectfully submits that new Claims 43-55 are also not described or suggested by Toppo because Toppo discloses the opposite (*i.e.*, "the drug must be stable, have a molecular weight less than 1000, a melting point less than about 93 degrees Celcius, a solubility in oil and water greater than 1 mg/ml and a pH of 5 to 9 in a saturated aqueous solution." Toppo at column 2, lines 16-20 (emphasis added).)

Accordingly, Applicant respectfully submits that the new claims and claims as amended are in condition for allowance.

CONCLUSION


In view of the above amendments and comments, Applicant believes that the instant application is in condition for allowance and such action is earnestly solicited. However, if any issues remain, the Examiner is respectfully requested to call Applicant's attorney, Eric S. Furman at (619) 687-8643 to resolve such matters promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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